

U.S. Patent Application Serial No. **10/606,803**  
Amendment filed April 27, 2006  
Reply to OA dated January 30, 2006

**REMARKS**

Claims 1-22 are pending in the application, with claims 13-22 currently withdrawn from the consideration. The present amendment cancels claims 13-22 without prejudice or disclaimer, and amends claims 1-12. Upon entry of this amendment, claims 1-12 will be pending. Entry of this amendment and reconsideration of the rejections are respectfully requested.

No new matter has been introduced by this Amendment. Support for the amendments to the claims is discussed below.

**Regarding the withdrawn claims.**

Claims 13-22 are canceled without prejudice or disclaimer.

**Claims 10 and 11 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or which it is most nearly connected, to make and/or use the invention. (Office Action, p.2)**

The Examiner refers to the STIP-1 cells (FERM BP-8421) and STIP-3 cells (FERM BP-8422), recited in claims 10 and 11, and refers to 37 CFR 1.801-1.809 regarding deposit of biological material necessary for meeting the requirements of 35 U.S.C. 112, first paragraph.

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Reconsideration of the rejection is requested in view of the amendment to the specification.

Applicant submits that the requirements of 37 CFR 1.801-1.809 have been fully met in the present application.

The present specification states on page 13 that STIP-1 cells (FERM BP-8421) and STIP-3 cells (FERM BP-8422) were deposited under the Budapest treaty, where they received the FERM deposition numbers.

Rule 1.804 covers the time of making an original deposit. Applicant notes that, in the present application, since the deposit was made **prior** to the filing date of the patent application, 1.804(b) is not relevant, and it is **not necessary** to make the statement under 1.804(b), or the additional declaration suggested by the Examiner.

In accordance with 37 CFR 1.809(d)(2) and (3), Applicant has amended the specification on page 13 to provide the additional details of the **date** of the deposit and the **address** of the depository (see 37 CFR 1.809(d)(2)). In addition, the specification has been amended to specify the complete taxonomic description of Bester for the STIP-1 and STIP-3 cells.

In addition, Applicant has attached to this Amendment copies of the Receipts in the Case of Original Deposit under the Budapest Treaty for the STIP-1 and STIP-3 cells.

**Claims 2-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. (Office Action, p.6)**

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The Examiner refers to the phrase “is used” in claims 2-11.

The rejection is overcome by the amendments to the claims, deleting the phrase “is used.”

For example, claim 2 has been amended to recite: “... wherein ~~an~~ said established cell line is of Bester origin ~~is used~~.” Applicant submits that these amendments represent only a grammatical clarification of the claims.

**Claims 1, 3 and 6-7 are rejected under 35 U.S.C. 102(b) as being anticipated by Watson et al. (Dis. Of Aquat. Org. 1998) (Office Action, p.7)**

The rejection is overcome by the amendment to claim 1, limiting the cell line to be “originated from sturgeon eyeball.” Support for this amendment may be found in the specification on page 5, lines 9-18.

Watson et al. discloses establishing sturgeon cell lines in column 174, column 1, last paragraph. However, there is no disclosure or suggestion in Watson et al. for cell lines originated from sturgeon eyeball.

**Claims 1-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Watson et al in view of Fent (Toxicol. In Vitro 2001), Hiramatsu et al. (Comp. Biochem. and Physiol. 2002), Babich et al. (Ecotoxic. and Envir. Safety 1987) and in view of Okamura et al. (Chemosphere). (Office Action, p. 7)**

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Reconsideration of the rejection is respectfully requested in view of the amendment to claim 1, limiting the cell line to be “originated from sturgeon eyeball.”

The Examiner cites Watson et al for using established Sturgeon cell lines in a toxicity assay. Fent is cited for the disclosure that cells from fish and fish cell lines can be used for the assessment of toxic action of chemicals (abstract).

The Examiner addresses the “ocular” limitation of claim 4 at the top of page 11 of the Office action, stating that it would be obvious to use a cell line from the eye, because “these cells would normally be among the first to be exposed to toxic substances in the water in which they live.”

Applicant submits that this is an improper motivation for the Examiner's proposed modification of the references. Applicant notes that MPEP 2143.01 states:

“Obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art.”

The motivation stated by the Examiner is clearly **not** found in the cited references. Applicant notes in this regard that Watson et al. states:

“To establish primary sturgeon cell cultures, tissues from olfactory organs, brain, swim bladder, liver, meningeal myeloid organ or cranial hematopoietic/granulopoietic organ ... and gonad were aseptically removed from a yearling sturgeon.” (page 174, column 1, last paragraph)

Gonad, meningeal myeloid organ, liver, swim bladder and brain cell lines were obtained, and these and spleen were used (page 17, column 2). There is clearly no disclosure of, or suggestion for, eyeball cell lines. Similarly, Fent discloses that numerous fish cell lines exist (page 479, column 2),

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but specifically uses a fish liver cell line in the cytotoxicity assay (Fig. 3), and has no disclosure of or suggestion for use of eyeball cell lines. Likewise, Babich et al. (pages 78 and 80) discloses RTG-2 cells, a fibroblastic line derived from rainbow trout, BF-2 cells, a fibroblastic line derived from bluegill sunfish, and FHM skin epithelial cells from fathead minnows. Hiramatsu et al. does not appear to disclose any sturgeon cell lines.

With regard to whether there is any motivation for the proposed modification in the general knowledge in the art, Applicant respectfully submits that the Examiner's stated rationale does not make sense. It is not really important which cells or tissues in the fish are "first to be exposed" to a toxin; many tissues in a fish will be exposed to a toxic compound and may experience toxicity. The motivation in the general art for selection of cell lines in a cytotoxicity assay would generally be which cells are most representative of the living fish. Fent notes: "Cytotoxicity was found in several studies to be correlated with in vivo acute fish toxicity" (page 480, column 2, line 11), a statement that does not suggest use of any particular cell line. The Examiner has cited no suggestion in the art that "ocular" or "eyeball" cells would be particularly representative of the living fish.

Applicant further notes the Examiner's comments on page 9, lines 12-16, of the Office action: "it would have been obvious and beneficial to one of ordinary skill in the art to seek and use a sensitive cell line ..." Applicant submits that this "obvious to seek" statement does **not** provide a proper suggestion or motivation for the specific limitations on cell lines recited in the present claims. By analogy, it might be "obvious" in the general art to seek a vaccine against AIDS, but this does not mean that any achieved vaccine against AIDS would be obvious and unpatentable.

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Finally, with regard to claim 10 and 11, Applicant notes that the Examiner has not provided any suggestion or motivation for the specific STIP-1 and STIP-3 cell lines recited in these claims.

Applicant therefore submits that claims 1-12, as amended, are not anticipated by, and are not obvious over Watson et al., Fent, Hiramatsu et al., Babich et al. and Okamura et al., taken separately or in combination.

If, for any reason, it is felt that this application is not now in condition for allowance, the Examiner is requested to contact the Applicant's undersigned agent at the telephone number indicated below to arrange for an interview to expedite the disposition of this case.

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In the event that this paper is not timely filed, the Applicant respectfully petitions for an appropriate extension of time. Please charge any fees for such an extension of time and any other fees which may be due with respect to this paper, to Deposit Account No. 01-2340.

Respectfully submitted,

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PATENT TRADEMARK OFFICE

Attachments: Receipt in the case of original deposit for STIP-1  
Receipt in the case of original deposit for STIP-3  
Information Disclosure Statement

H:\HOME\XLU\030\030791\Amendment in re OA of Jan. 30, 2006